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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,230	07/01/2005	Gijs Robert Van Den Brink	28902.nob10	1902

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EXAMINER	
HOWARD, ZACHARY C	
ART UNIT	PAPER NUMBER
1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,230	VAN DEN BRINK ET AL.	
	Examiner	Art Unit	
	Zachary C. Howard	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The preliminary amendment of 8/20/2004 has been entered in full. Claims 14-24 are canceled. Claims 1-10, 12, 13 and 25-29 are amended. New claims 30-33 are added.

Claims 1-13 and 25-33 are pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-13, 30 and 31, drawn to a method of treating a deficiency of a Hedgehog protein in the GI tract of a subject comprising providing to the GI tract a composition comprising a source of a Hedgehog protein.

Group II, claims 25 and 26, drawn to a method of determining whether a subject is at risk for developing a GI tract tumor comprising measuring the level of Hedgehog protein or mRNA in a GI tract tissue sample.

Group III, claim 27, drawn to a method of diagnosing the presence of ectopic gastric tissue, or susceptibility of developing such, comprising determining the level of Hedgehog, BMP2 or BMP4 mRNA.

Group IV, claims 28 and 29, drawn to a therapeutic composition comprising a nucleic acid in the form of a expression vector encoding a Hedgehog protein or an enteric bacterium comprising the nucleic acid sequence.

Group V, claims 32 and 33, drawn to a method for preventing the development for treating a disease or condition characterized by the presence or growth of a Hedgehog protein-expressing ectopic gastric tissue in a subject, comprising providing to the subject an effective amount of a substance that reduces the functional level or activity of the Hedgehog protein.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Pursuant to 37 C.F.R. 1.475 (B-D), the ISA/US considers that where multiple products are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, in this case the main invention would consist of the first method (Group I) and the first (and only, in this case) claimed product used in said method (the composition of Group IV). However, the technical feature linking groups I and IV appears to be that they relate to a composition comprising a nucleic acid and methods of treatment that encompass use of said composition.

However, the prior art teaches a composition that is encompassed by the composition of Group IV. Specifically, Ingham et al, U.S. Patent 6,165,747, published 12/26/00, teaches compositions comprising an expression vector comprising a nucleic acid encoding a Hedgehog protein. Ingham teaches that "the present invention relates to nucleic acids encoding vertebrate hedgehog proteins...and preparations of such compositions" (col. 16, lines 21-26) and "expression constructs of the subject vertebrate hh polypeptide, and mutants thereof, may be administered in any biologically effective carrier, e.g. any formulation or composition capable of effectively delivering the recombinant gene to cells in vivo" (col. 26, lines 35-39). Such compositions are encompassed by the compositions of Group IV. Therefore, the technical feature linking the inventions of group I and IV does not constitute a special technical feature as defined by PCT rule 13.2, as it does not define a contribution over the prior art.

The methods of Groups II, III and V are different methods of using different products from those of Group I and therefore are not considered to be part of the main invention according to 37 C.F.R. 1.475 (B-D).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Elections of Species

In addition to the above restriction requirement, the following elections of species are required, dependent on which Group is elected.

(1) If Group I or Group IV is elected, the following election of species is required. Groups I or IV contain claims directed to more than one species of a source of a Hedgehog protein of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: (1) Hedgehog protein (including homologues and variants of said protein); (2) nucleic acid expression vector; (3) enteric bacteria capable of colonizing the GI tract that expresses and secretes Hedgehog protein; (4) animal cell that expresses and secretes Hedgehog protein; and (5) molecule or agent that induces or upregulates Hedgehog protein.

Applicant is required, in reply to this action, to elect a single species of source of a Hedgehog protein to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). The claims are deemed to correspond to the species of cancer listed above in the following manner:

1. Claims 1-7 are generic.
2. Claims 8, 9, 30 and 31 correspond to each species.
3. Claims 10 and 11 correspond to the species of Hedgehog protein.
4. Claim 12 corresponds to the species of nucleic acid.
5. Claim 13 and 29 correspond to the species of enteric bacterium.
6. Claim 28 corresponds to the species of nucleic acid and enteric bacterium.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each source is a molecule or cell that is structurally distinct from the other molecules and cells. Lack of unity is shown because these molecules lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

(2) If Group I or II is elected, the following election of species is required. Groups I and II contains claims directed to more than one species of cancer the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: gastric cancer, colon (large intestinal) cancer, small intestinal cancer, or esophageal cancer.

Applicant is required, in reply to this action, to elect a single species of cancer to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any

claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). The claims are deemed to correspond to the species of cancer listed above in the following manner:

1. Claims 1, 2, 4, 6, 10-13, 25, 30 and 31 are generic.

2. Claims 3 and 5 each correspond to the species of gastric and colon cancer.

3. Claims 7-9 correspond to colon cancer because these claims are directed to "familial adenomatous polyposis coli (FAP)", which leads to colon cancer.

4. Claim 26 corresponds to the species of gastric, esophageal and colon cancer.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each type of cancer is has a different source tissue, etiology and treatment. Lack of unity is shown because the cancers lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

(3) If Group V is elected, the following election of species is required. Group V contains claims directed to more than one species of a substance that reduces functional level or activity of a Hedgehog protein of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: (1) antibody specific for human Desert Hedgehog protein of SEQ ID NO: 1; (2) antibody specific for human Indian Hedgehog protein of SEQ ID NO: 2; (3) antibody specific for human Sonic Hedgehog protein of SEQ ID NO: 3; (4) antisense sequence complementary to mRNA that encodes human Desert Hedgehog protein of SEQ ID NO: 1; (5) antisense sequence complementary to mRNA

that encodes human Indian Hedgehog protein of SEQ ID NO: 2; (6) antisense sequence complementary to mRNA that encodes human Sonic Hedgehog protein of SEQ ID NO: 3;

Applicant is required, in reply to this action, to elect a single species of substance that reduces functional level or activity of a Hedgehog protein to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). The claims are deemed to correspond to the species of cancer listed above in the following manner:

1. Claims 32 is generic.
2. Claim 33 corresponds to each species.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each antibody or antisense sequence is a molecule that is structurally distinct from the other antibodies and antisense sequences. Lack of unity is shown because these molecules lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

zch

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646